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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,572	04/28/2006	Ushio Iwamoto	P28765	8899
7055 7590 04/06/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER UNDERDAHL, THANE E				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
04/06/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/559,572

Applicant(s)

IWAMOTO ET AL.

Examiner

THANE UNDERDAHL

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-139 is/are pending in the application.
- 4a) Of the above claim(s) 91-104 and 121-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-120 and 137-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/08 has been entered.

This Office Action is in response to the Applicant's request for continued examination received 12/29/08. Claims 91-139 are pending. Claims 91-104 and 121-136 are withdrawn. Claims 1-90 are cancelled. Claims 105, 107 have been amended. Claim 139 is new. Claims 105-120 and 137-139 are considered in this Office Action.

Response to Applicant's Amendments

In the response submitted by the Applicant the 35 U.S.C § 102 (b) and 103 (a) rejection of claims 105-120, 137 and 138 based on Slepian et al. alone and in view of other references are withdrawn in light of applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 105 and 120 are rejected under 35 U.S.C. 102(b) as being anticipated by Read et al. (U.S. Patent # 5651966, 1997) with support by Wakelyn et al. (Handbook of Fiber Chemistry, 1998).

These claims are to a method of preparing a wound-healing promoting material comprising the following steps:

- o Extracorporeally contacting at least one of leukocytes and platelets with a sheet-shaped porous body to trap them on the surface of the pores.

Read et al. teach that bandages can be made from woven or nonwoven cotton (col 4, lines 50-60). They teach these bandages are contacted with an aqueous solution of platelets which causes them to adhere to the cotton (col 4, lines 30-35). Woven or nonwoven cotton inherently has pores as supported by Wakelyn et al. and also since cotton sheets are a collection of overlaid fibers that inherently form pores (see M.P.E.P. § 2112 IV for Examiner's Burden of Inherency).

Therefore the references anticipate claims 105 and 120.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105-107, 115, and 120 rejected under 35 U.S.C. 103(a) as being unpatentable over Read et al. (U.S. Patent # 5651966, 1997) as applied to 105 and 120 above and for further rational below and in light of support by Seagull et al. (J. Cotton Science).

Claims 106 and 107 define the dimensions of the fabric and limit it to a nonwoven fabric. Read et al. teach that their bandage is made of nonwoven cotton. However they do not explicitly teach the diameter of the cotton fibers. However as supported by Seagull et al. common cotton fibers used in textiles have a diameter between 14 and 28 micrometers (pg 100, Figure 2). Therefore it would be obvious that the cotton of Read et al. would have a diameter between 0.3 to 50 micrometers. What Read et al. does not teach is the thickness or the bulk density of the cotton bandage. However, one of ordinary skill in the art would recognize that the size and density of the cotton bandage are result effective variables. This would depend on the use, the type and size of the wound the bandage is expected to cover and the amount of bleeding expected. Indeed one of ordinary skill in the art would recognize that a common drug store or first aid kit has a multitude of bandages ranging from small circles for paper cuts to thick, absorbent self-adhesive pads for more severe injuries. Absent any teaching of criticality by the applicant concerning these limitations, it would be *prima facie* obvious that one of ordinary skill in the art would recognize these limitations are result effective variables which can be met as a matter of routine optimization (M.P.E.P. § 2144.05 II).

Claim 115 limits that the sheet-shaped porous body with platelets is further cultured. Read et al. teach that bandages, mesh and dressing that are impregnated

with platelets induce wound healing (Example 10). One of ordinary skill in the art would recognize that since wound healing occurred and was accelerated after the dressing was applied and the healing was accelerated by the dressing, then it obviously the dressing with platelets took part in the culturing of new cells to heal the wound.

Therefore claims 105-107, 115, and 120 are obvious in view of the above reference.

Claim Rejections - 35 USC § 103

Claims 105-115, 118-120 and 137-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read et al. (U.S. Patent # 5651966, 1997) as applied to claims 105-107, 115, and 120 above, and further in view of Onodera et al. (U.S. Patent # 5407581, 1995) in light of support of Jan et al. (J. General Physiology, 1973).

While Read et al. does teach a wound healing material with platelets attached to the surface of the pores in a sheet, they do not teach that the platelets were obtained by the filtering steps limited in the claims or that the source is fresh blood filtered in through the sheet. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Onodera et al.

Onodera et al. teach that the surface of filter media such as cotton and porous sponges can be modified via methods such as graft copolymerization, radiation or plasma treatment, or covalent bonding of ligands on the surface (Onodera et al. col 16, lines 1-10). Onodera et al. teach that the purpose of these modifications is to obtain a filter media with a surface electric charge of greater than -30 $\mu\text{eg/g}$ (Onodera, col 5, lines 10-15). Onodera et al. teach that as the surface electric charge is increased then

the adhesion of platelets is increased (Onodera et al. col 17, lines 45-47). Onodera et al. also teach that modifying the pores size of the sheets can also increase the affinity of platelets (Onodera et al. col 21, lines 5-12). Indeed Onodera et al. teach the pore size should be from 1 to 100 μm (col 14, lines 20-25). Onodera et al. teach that leukocytes are selectively bound to a sheet with this negative surface electric charge (Onodera, col 23, lines 30-35). This charge interaction would inherently exclude erythrocytes since their surface is negatively charged and thus repelled by a negative surface charge as supported by Jan et al. (Introduction, 1st paragraph).

Onodera et al. also teach that the porous sheet can be placed inside an openable container with an inlet and outlet ports (Onodera, col 23, lines 33-44 and Example 26). Onodera et al. teach that extracorporeal blood products such as plasma, fresh whole blood, leukocyte-containing red cell product, leukocyte containing platelet product or leukocyte containing plasma product can be passed immediately through the filter via the inlet ports and outlet ports (Onodera, col 23, lines 33-44, col 27, lines 33-37 and Example 26). Onodera et al. teach that the filter is washed since the porous sheet is continuously flushed with the sample even after initial contact with the blood cell suspension (Example 21, col 65, lines 30-45). Therefore one of ordinary skill in the art would recognize that the initial blood placed into the suspension would initially bind the platelets or leukocytes and the remaining blood would wash over those initially bound platelets.

In the example by Onodera et al. they do not specifically mention that the container is liquid tight. However one of ordinary skill in the art would read that the

container of Onodera et al. did not spill or leak and that spilling blood products is a potential biohazard, therefore it would be obvious to one of ordinary skill in the art to make the container liquid tight. Also Onodera et al. does not teach the exact source of his blood, however they do teach that the treatments are for humans (Onodera, col 10, line 9, col 14, line 59, col 27, lines 19) it would be obvious to one of ordinary skill in the art to use human blood which has mature cells such as erythrocytes. Furthermore it would be obvious to one of ordinary skill in the art to use either autologous blood or blood from a matching donor since both are art-recognized equivalents for the same purpose (M.P.E.P. § 2144.06).

It would be obvious to one of ordinary skill in the art to combine the teachings of Onodera et al. with Read et al. since both share common materials such as cotton to teach a method that at the very least trap platelets. Read et al. desires to attach platelets to their cotton bandage. Onodera et al. teaches methods of modifying cotton and other material to provide both pore size and surface charge to selectively adhere platelets. Therefore one of ordinary skill in the art would recognize that the known work in the field taught by Onodera et al. would prompt a variation in the bandage of Read et al. since they teach the same materials as well as a common goal to selectively adhere platelets to that common material ((KSR International v. Teleflex Inc. 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007))).

Therefore claims 105-115, 118-120 and 137-139 are obvious in view of the above references.

Claims 105-107, 115-117, and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read et al. (U.S. Patent # 5651966, 1997) as applied to claims 105-107, 115, and 120 above, and further in view of Britton et al. (U.S. Patent Publication # 2003/007957, January 2003).

While Read et al. teach a sheet shaped porous body with platelets trapped on the surface. They do not teach the addition of fibroblasts or fibrins. Regardless this would be obvious in view of Britton et al. They desire to make a bandage impregnated with an autologous platelet-rich plasma as a pharmaceutical preparation to accelerate wound healing (Britton, Abstract and paragraph 33). They teach that their platelet rich plasma comprises platelets, white blood cells (leukocytes), plasma and plasma proteins (Britton, paragraph 8). It would be obvious to combine the teachings of Britton with the bandage of Read et al. since both are directed towards wound healing and both incorporate platelets into a bandage. Therefore this is simply using the teachings of Britton et al. to improve a similar bandage of Read et al. that already incorporates some of the materials such as platelets impregnated on a bandage, as Britton ((KSR International v. Teleflex Inc. 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007))).

Therefore claims 105-107, 115-117, and 120 are obvious in view of the above references.

No claims are currently allowed in this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651